

REMARKS

Claims 1-60 are pending in the instant application.

Claims 5, 6, 8, 12, and 29-60 have been withdrawn from consideration by the Examiner. Applicants understand that upon allowance of a generic Claim, Claims to non-elected species will be given further consideration, as provided under M.P.E.P. §809.02(c).

Claims 1-4, 7, 9-11, and 13-28 are currently presented for examination. Claims 1-4, 7, 9, 13, 14, 22, and 26-28 are rejected, and Claims 24 and 25 are objected to.

Claims 2, 7, 9, 13, 14, 22, and 24-26 have been amended. The amendments to Claims 2, 7, and 24-26 address informalities, and support for these amendments can be found throughout the specification, including the originally filed Claims. Support for the amendment of Claim 9 can be found at page 2, lines 30-31; page 3, lines 31-32; page 4, lines 1-4; page 13, lines 1-30; page 26, lines 9-23; Fig. 4, and elsewhere throughout the specification. Support for the amendment of Claim 13 can be found at page 4, lines 5-11, and elsewhere throughout the specification, including originally filed Claim 13. Support for the amendment of Claim 14 can be found at page 2, lines 28-30, and elsewhere throughout the specification, including the originally filed Claims. Support for the amendment of Claim 22 can be found at page 5, lines 17-26, and elsewhere throughout the specification, including the originally filed Claims. Accordingly, no new matter has been added to the instant application.

After careful consideration of the Office Action, Applicants respectfully traverse the Examiner's objections and claim rejections below.

Objection to the Specification

The Examiner objects to the Abstract of the Disclosure as allegedly exceeding 150 words. Applicants have amended the abstract. The amended abstract is less than 150 words.

Claim Objections

The Examiner objects to Claims 24 and 25 as including certain informalities. Applicants have amended Claims 24 and 25 in accordance with the Examiner's suggestions.

Rejections Under 35 U.S.C. 112, Second Paragraph

Claims 2-4, 7, 9, 13, 14, 22, and 26-28 are rejected under 35 U.S.C. 112, second paragraph as allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention. Each of these rejections is addressed in detail below.

Claim 2

Claim 2 is rejected as vague and indefinite because the phrase "the isolating includes subjecting the mixture to a magnetic field" is allegedly incomplete. Applicants maintain that Claim 2 is clear as originally filed, however, in order to expedite allowance, Applicants have amended the cited phrase in accordance with the Examiner's suggestion to read "the isolating the dual bead complex includes subjecting the mixture to a magnetic field." Applicants therefore request withdrawal of the rejection of Claim 2.

Claim 3

Claims 3 is rejected as vague and indefinite because it provides that "the magnetic field is applied while the capture beads and reporter beads are on the disc," but the exposing step in Claim 1 is allegedly after the isolating step, and in view of Claim 2 the magnetic field allegedly must be applied before the capture beads and reporter beads are on the disc.

Applicants respectfully disagree with the Examiner's characterization of Claims 1 and 2. Applicants submit that one of skill in the art would understand that the method of Claim 1, from which Claims 2 and 3 depend, uses the open-ended transitional phrase comprising, and thus may include steps in addition to those recited in the Claim. Accordingly, the mixing or isolating steps in Claim 1 could be preceded by the step of loading the mixture onto a biodisc. Claim 2 therefore does not require the magnetic field to be applied before the capture beads and reporter beads are on the disc, since the step of exposing the isolated dual bead complex to a capture field on a disc does not preclude a preceding step of loading the mixture or the isolate onto a biodisc. Thus, a skilled artisan would recognize that, in some embodiments, a mixture could be loaded onto a disc, the dual bead complexes could be isolated using a magnetic field while on the disc, and the isolate could then be exposed to a capture zone on the disc. In light of the above arguments, Applicants respectfully request withdrawal of the rejection of Claim 3 under section 112.

Claim 4

Claim 4 is rejected as vague and indefinite because the phrase "the capture beads and reporter beads are mixed off the disc and the magnetic field is applied to the mixture of the sample and the beads off the disc" allegedly does not make sense because the exposing step in Claim 1 is allegedly after the isolating step, and in view of Claim 2 the magnetic field allegedly must be applied before the capture beads and reporter beads are on the disc.

Applicants respectfully submit that Claim 4 is not vague or indefinite in light of the arguments presented in connection with Applicants' response to the rejection of Claim 3. In particular, there is nothing in Claims 1 or 2 that requires the mixing of capture beads and reporter beads or the application of the magnetic field to occur either on or off the disc. The language of Claim 4 cited by the Examiner simply specifies that the mixing and the application of the magnetic field occur off the disc. Accordingly, Applicants submit that Claim 4 as written is not vague or indefinite, and respectfully request withdrawal of the rejection of Claim 4 under section 112.

Claim 7

Claim 7 is rejected as vague and indefinite because the phrase "the detecting includes directing light to the capture field and detecting light reflected from the capture field" is allegedly incomplete. Applicants maintain that Claim 7 is clear as originally filed, however, in order to expedite allowance, Applicants have amended the cited phrase in accordance with the Examiner's suggestion to read "the detecting the presence of the dual bead complex includes directing light to the capture field and detecting light reflected from the capture field." Applicants therefore respectfully request withdrawal of the rejection of Claim 7.

Claim 9

Claim 9 is rejected as vague and indefinite because the phrase "the reporter beads are fluorescent, the detecting including directing light at a wavelength at which the reporter beads fluoresce, and detecting light at a wavelength emitted by the reporter beads" is allegedly unclear. The Examiner's suggested amendment particularly identifies one embodiment of the claimed subject matter. However, Applicants respectfully submit that the Claim need not be so limited. For example, the Claim as amended by Applicants can include beads comprised of fluorescent materials as well as non-fluorescent beads labeled with fluorescent molecules, among other things, whereas the Examiner's proposed amendment would likely include only the latter.

Accordingly, Applicants have amended the cited phrase to read "the reporter beads are fluorescent, and the detecting the presence of the dual bead complex further comprises directing light at a wavelength at which the reporter beads fluoresce and detecting light at a wavelength emitted by the reporter beads." Applicants submit that claim 9 as amended is clear and not vague or indefinite. Accordingly, Applicants respectfully request withdrawal of the rejection of Claim 9.

Claim 13

Claim 13 is rejected as vague and indefinite because it is allegedly unclear whether the biological sample in Claim 1 includes all samples in Claim 13, or whether a biological sample in Claim 1 is selected from one of the samples in Claim 13. Claim 13 has been amended to recite the biological samples in Markush format. In particular, Claim 13 has been amended to recite, "wherein the biological sample is selected from the group consisting of blood, serum, ..., a tissue, and a tissue extract." Accordingly, Applicants respectfully request withdrawal of the rejection of Claim 13.

Claim 14

Claim 14 is rejected as vague and indefinite because the phrase "the reporter bead includes latex, gold, plastic, steel, or titanium" is allegedly unclear. Applicants maintain that Claim 14 is clear as originally filed, however, in order to expedite allowance, Applicants have amended the identified phrase to read "the reporter beads comprise latex, gold, plastic, steel, or titanium." Applicants submit that the amended Claim is not vague or indefinite, and thus respectfully request withdrawal of the rejection of Claim 14.

Claim 22

Claim 22 is rejected as vague and indefinite because it is allegedly unclear whether the target agent in Claim 1 includes all target agents in Claim 22, or is selected from one of the nucleic acids of Claim 22. Claim 22 has been amended to recite the target agents in Markush format. In particular, Claim 22 has been amended to recite "wherein the target agent is selected from the group consisting of a nucleic acid characteristic of a disease, ..., a viral protein antigen, and a protein characteristic of a disease state in a subject." Accordingly, Applicants respectfully request withdrawal of the rejection of Claim 22.

Claim 26

Claim 26 is rejected as vague and indefinite because the meaning of the phrase "a second capture field fluidly coupled to the first capture field" is allegedly unclear. Applicants maintain that Claim 26 is clear as originally filed, however, in order to expedite allowance, Applicants have amended the cited phrase to read "a second capture field coupled to the first capture field." Applicants submit that amended Claim 26 is not vague or indefinite, and accordingly request withdrawal of the rejection.

Claim 26 is also rejected as vague and indefinite because it allegedly does not correspond to Claim 1, since Claim 1 allegedly requires one capture field while Claim 26 has two capture fields. Applicants respectfully disagree with the Examiner's reading of Claim 1. Claim 1 is directed to a method comprising a number of steps, one of which is "exposing the isolate to a capture field on a disc...." Claim 1 in no way requires that there is only one capture field. Rather, it simply requires that one of the steps of the method is "exposing the isolate to a capture field on a disc..." Thus, the recitation in Claim 26 of "a chamber within the disc, the chamber including a first capture field and a second capture field...", is not inconsistent with Claim 1. Accordingly, Applicants respectfully request withdrawal of the rejection of Claim 26.

Claims 27 and 28

Claims 27 and 28 are rejected as vague and indefinite because they allegedly do not correspond to Claim 1. In particular, the Examiner asserts that Claim 1 requires one capture field and one capture agent while Claims 27 and 28 allegedly have two capture fields and two capture agents. As described in connection with Applicants' response to the rejection of Claim 26, Applicants submit that Claim 1 in no way requires only one capture field and/or one capture agent. Claim 1 requires only that the method comprises the step of "exposing the isolate to a capture field on a disc, the capture field having a capture agent that binds to the dual bead complex." Thus, the recitation in Claim 27 of "....providing a first capture agent in the first capture field, and a second agent, different from the first capture agent, in the second field," and the recitation in Claim 28 of "...providing a first capture agent and a second capture agent, different from the first capture agent, in the same capture field..." are not inconsistent with Claim 1. Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 27 and 28.

Obviousness-Type Double Patenting Rejection of Claim 1

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting over Claim 1 of co-pending Application No. 10/087,549. Applicants note that this double patenting rejection would become manifest only after the issuance of Claims of co-pending Application No. 10/087,549. Accordingly, Applicants maintain that it is presently premature to respond to an obviousness-type double patenting rejection in view of the Claims of co-pending Application No. 10/087,549, as neither the Claims in the present application nor the Claims of co-pending Application No. 10/087,549 have specifically been allowed at this time. Applicants do not concede that the Claims in either application are obvious over one another.

CONCLUSION

Applicants believe that all of the objections and grounds for Claim rejections set forth in the aforementioned Office Action have been overcome in view of the Amendments to the Claims and Remarks set forth above. The Examiner is invited to contact the undersigned at the telephone number provided below in order to facilitate the submission of a terminal disclaimer so that the application may proceed to allowance.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Nov 23, 2004

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